IN THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION	**CASE NO. 1:17-MD-2804** **JUDGE DAN A. POLSTER** **MAGISTRATE JUDGE DAVID A. RUIZ** **REPLY TO BRIEF OF CERTAIN DEFENDANTS' OBJECTIONS TO PROPOSED ORDER DE-DESIGNATING SUSPICIOUS ORDER REPORTS AND TO DEA BRIEF IN SUPPORT OF MAINTAINING THE COURT'S PROTECTIVE ORDER** **FILED ON BEHALF OF HD MEDIA COMPANY, LLC, *dba* CHARLESTON GAZETTE-MAIL**

HD MEDIA COMPANY, LLC, *dba Charleston Gazette-Mail*, ("Media Intervenor"), submits the following reply to Certain Defendants' objections to the proposed order de-designating DEA suspicious order reports and to the DEA brief in support of maintaining the Court's protective order with respect to 2013-2014 ARCOS Data.[1]

I. INTRODUCTION

In accord with this Court's instructions, representatives of the Media Intervenors, the DEA and the Pharmaceutical Company Defendants met and conferred seeking to determine if areas of agreement existed with regard to modifying the existing protective order. The DEA and the Media Intervenors submitted a proposed order on July 26, 2019, ECF 2040. If entered, it would de-designate certain documents — suspicious order reports (SORS) — under the

[1]HD Media incorporates herein by reference the arguments set forth in *The Washington Post*'s "Response to Certain Defendants' Objection to Proposed Order De-Designating DEA Suspicious Order Reports and Media Intervenors Position Paper."

Protective Order. The proposal also provides DEA additional time to determine whether additional SORS and related material may be de-designated.

Subsequently, "Certain Defendants" filed objections to the proposed de-designation order; he DEA submitted a brief in support of maintaining the existing protective order as to 2013-2014 ARCOS data. This reply responds to the issues they raise.

II. THE APPROPRIATE STANDARD FOR DETERMINING GOOD CAUSE FOR A PROTECTIVE ORDER UNDER RULE 26(c)

Certain Defendants' objections to the proposed agreed order are based upon their erroneous assertion that "discovery material that is not attached to any court filing simply is not a judicial record that should be disclosed to the public." (Case 1:17-md-02804, Doc #2080, Page ID#286626.) The defendants fail to acknowledge that the Media Intervenors have not asserted SORS are "court filings" or otherwise "docketed court records."

The actual issue before the Court is whether the existing protective order should continue to apply to SORS and 2013-2014 ARCOS data. The Court of Appeals for the Sixth Circuit set forth the applicable law in *In re National Prescription Opiate Litigation*, 927 F.3d 919, 931 (6th Cir. 2019) ("[d]espite the 'substantial latitude' afforded to district courts during the discovery process . . . In considering whether good cause for protection exists, we balance the interests in favor of disclosure against the interests in favor of nondisclosure.").[2]

[2] The Court distinguished *Seattle Times Co. v. Rhinehart*, 467 U.S. 20, 36, (1984)). Unlike the conclusory assertions made by the defendants, the party seeking a protective order in *Seattle Times* supported its request with particularized facts that the state trial court found constituted good cause under Washington Superior Court Civil Rule 26(c):

> They submitted affidavits of several Foundation members to support their request [for a protective order]. The affidavits detailed a series of letters and telephone calls defaming the Foundation, its members, and Rhinehart—including several that threatened physical harm to those associated with the Foundation. The affiants also described incidents at the Foundation's

As the Sixth Circuit emphasized, a party seeking a protective order bears the burden of showing good cause. 927 F.3d at 929 ("A protective order shall only be entered upon a showing of 'good cause' by the party seeking protection.") (citing Fed. R. Civ. P. 26(c)(1). "To show good cause for a protective order, the moving party is required to make 'a particular and specific demonstration of fact, as distinguished from stereotyped and conclusory statements.'" *Id.* (quoting *Nemir v. Mitsubishi Motors Corp.*, 381 F.3d 540, 550 (6th Cir. 2004)). On this basis, this Court must determine whether the existing protective order is appropriately supported by Rule 26(c) good cause. As explained below, neither defendants nor the DEA have met their Rule 26(c) burden.

III. THE DEFENDANTS HAVE FAILED TO ESTABLISH GOOD CAUSE WITH PARTICULAR AND SPECIFIC FACTS TO SUPPORT THE ISSUANCE OF A PROTECTIVE ORDER UNDER RULE 26(c).

Certain Defendants support their argument that SORS should be subject to a protective order based on the bald contention that SORS were "provided to the DEA under an assumption of confidentiality," "were marked confidential by DEA when they were produced in this litigation," are "maintained by Defendants as confidential business data that is not shared with the public," and "implicate the privacy interests of third parties identified in the reports."[3] Case 1:17-md-02804, Doc #2080, Page ID# 286627. These unsupported assertions are woefully

> headquarters involving attacks, threats, and assaults directed at Foundation members by anonymous individuals and groups. In general, the affidavits averred that public release of the donor lists would adversely affect Foundation membership and income and would subject its members to additional harassment and reprisals.

Seattle Times, 467 U.S. at 26-27.

[3] Defendant's make the conclusory assertion that third party privacy would be compromised if the existing protective order no longer governed SORS, However, entities mentioned in SORS are not individual persons. SORS data is not personal in nature; it simply discloses volume and dosage of prescription opioids ordered f by a pharmacy. Where an incidental SORS references to an individual, identity of can be redacted on a showing of good cause.

inadequate to sustain a finding of good cause. Indeed, nowhere do the defendants mention or acknowledge the applicability of the "good cause" standard of Rule 26(c).

Moreover, Certain Defendants' reliance on *Food Marketing Institute v. Argus Leader Media*, 139 S. Ct. 2356 (2019), is misplaced as this Court previously held.[4] (*Order Amending Procedures Regarding Redactions And Filing Of Briefs Under Seal*, Doc #: 1813 PageID #: 54216, 54218-19.) Here, the issue is whether good cause exists under Rule 26(c) to support a protective order preventing disclosure of SORS - not whether a FOIA requester is entitled to disclosure of DEA-held documents. This Court should give no weight to Certain Defendants' erroneous interpretation of *Food Marketing*.

In *Prescription Opiate Litigation*, the Sixth Circuit held that the DEA and the defendants failed to show good cause with particularity to overcome the substantial public interest in disclosure necessary to keep the ARCOS data secret from the public:

> Intervenors, as representatives of the public, have a substantial interest in disclosure of the ARCOS data, while the DEA and Defendants have only a lesser interest in avoiding potential harms that can be avoided by narrower, less categorical means. The district court correctly observed that the ARCOS data 'provid[es] invaluable, highly-specific information regarding historic patterns of opioid sales.' (R. 397, Page ID# 5323.) The ARCOS data will aid us in understanding the full enormity of the opioid epidemic and might thereby aid us in ending it.

927 F.3d at 933.

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[4] Certain Defendants do not mention that *Food Marketing* interpreted an earlier version of FOIA that was amended in 2016. The recent amendments to FOIA impose a "foreseeable harm" requirement to prevent agencies from unnecessarily withholding records from the public. See S. Rep. No. 114–4, at 2–3 (2015). Under this requirement, a record that falls within the scope of one of FOIA's enumerated, discretionary exemptions cannot be withheld unless the agency also "reasonably foresees that disclosure would harm an interest protected by [that] exemption." 5 U.S.C. § 552(a)(8)(A); see also FOIA Improvement Act of 2016, Pub. L. No. 114–185, 130 Stat. 538, 539 (2016).

SORS are analogous to ARCOS data that was the focus of the appeal in *Prescription Opiate Litigation*. No SORS should be subject to a protective order unless a proponent of such an order makes "a particular and specific demonstration of fact, as distinguished from stereotyped and conclusory statements." *Id.* at 929.

While defendants assert SORS are cloaked with an "assumption of confidentiality" and "were marked confidential by DEA when they were produced in this litigation," that assumption is not supported by law or fact and is belied by the facts. There are no requirements, contractual or otherwise, that require pharmacies, manufacturers and distributors to maintain the confidentiality of such information. Such information is frequently communicated between and among them as part of the competitive prescription opioid marketing process. *See* Energy and Commerce Committee, *Red Flags and Warning Signs Ignored: Opioid Distribution and Enforcement Concerns in West Virginia*, at 136-40, 174-77 (December 19, 2018), available at https://www.ruralhealthinfo.org/assets/2616-9819/Opioid-Distribution-Report-FinalREV.pdf (hereinafter "Committee Report").

The DEA has now conceded that at least a substantial number of SORS formerly designated by the agency as confidential should be de-designated. Moreover, in 2016, the West Virginia Board of Pharmacy provided copies of 7000 pages of SORS to a reporter upon request. *See* Doc #725, PageID #16604-16605; Doc #725-3, PageID #16638, 16654-16670 (7000 pages of West Virginia SORS released by the West Virginia Bureau of Pharmacy and

referenced in newspaper articles published in December 2016).[5]

Importantly, the defendants' and the DEA's activities in using SORS to interdict diversion of prescription opioids has been scrutinized by the U.S. House Committee on Energy and Commerce. That Committee investigated opioid distribution in West Virginia. The report is replete with references to, and discussions of, suspicious order reports that were or should have been filed with the DEA. Committee Report at 5-8, 10, 16-18, 24, 28-29, 31, 34-40, 60-65, 88, 99, 102, 105-08, 115, 118, 172, 180-86, 189, 191, 193-96, 199-200, 210, 212-13, 220, 222, 228-325.

The Committee Report identifies failures of pharmaceutical companies and the DEA to use the suspicious order regulatory regime to interdict prescription opioid diversion; SORS of McKesson Corporation, AmerisourceBergen Drug Corporation and Cardinal Health are attached to the Committee Report.[6] The Committee found that drug distributors often failed to follow suspicious order monitoring requirements.[7] The Committee Report found "McKesson

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[5] The operative language of the DEA suspicious order rule and the West Virginia Board of Pharmacy SORS rule is identical. *Compare* 21 C.F.R. §1301.74 (b), *with* W. Va. Code R. § 15-2-4.4 (2014). Other states require defendants to file SORS. Certain Defendants cite no law *requiring* either DEA or corollary state agencies to withhold SORS from public scrutiny. Moreover, *The Charleston Gazette-Mail* has publicly identified specific pharmacies identified in SORS by opioid distributors. Eyre Affidavit, Doc #725-3, PageID #16635 at ¶¶ 16-18.

[6] *See Red Flags and Warning Signs Ignored: Opioid Distribution and Enforcement Concerns in West Virginia*, Subcommittee On Oversight And Investigations Document Binder, May 8, 2018, https://docs.house.gov/meetings/IF/IF02/20180508/108260/HHRG-115-IF02-20180508-SD005.pdf (Tab 8, 2006 – 2017, Suspicious Orders Reported by McKesson Corporation to the DEA for WV Customers; Tab 38, 2006 – 2017, Suspicious Orders Reported by AmerisourceBergen Drug Corporation to the DEA for WV Customers; Tab 56, 2006 – 2017, Suspicious Orders Reported by Cardinal Health to the DEA for WV Customers).

[7] The Committee found:

> [T]he companies . . . failed to address suspicious order monitoring in critical ways. Rather than reporting individual suspicious orders as they were identified,

did not submit suspicious order reports to the DEA regarding orders placed by West Virginia pharmacies until August 1, 2013[,]" but then it "submitted over 10,000 suspicious order reports to the DEA related to orders placed by West Virginia pharmacies" between August 1, 2013, and December 18, 2017. Committee Report, p. 16. As another example, "Cardinal did not have a consolidated suspicious order reporting system in place until 2012 and was unable to produce comprehensive suspicious order reports regarding West Virginia pharmacies prior to 2012." *Id.*

No absolute expectation of confidentiality or prohibition of disclosure of SORS data or ARCOS data exists under federal or state law. Manufacturers, distributors, and pharmacies in the prescription opioid supply chain are identified in the previously released 2006-2012 ARCOS data and publicly available SORS reports. United States opioid drug distributors, manufacturers, and pharmacies were, and are, well aware that any or all of this historic/stale information could be disclosed to the public by state regulatory agencies or the DEA.

The same good cause standard the Sixth Circuit applied to ARCOS data is applicable to SORS. Certain Defendants have not provided "particular and specific demonstration of fact" to support a finding of good cause. Balancing Certain Defendants' conclusory assertions in opposition to disclosure of SORS against the extraordinary public interest in favor of

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> some distributors reported a variety of other types information to DEA over the years. This information included excessive orders encompassing drug shipments that had already been shipped, and suspicious customers such as pharmacies with which distributors had terminated business relationships. Neither of these types of reports informed DEA about suspicious orders in real-time nor did they guarantee the suspicious orders reported to DEA were also blocked by the distributors. The Committee also found that one distributor lacked any formal order monitoring program. Rather, the distributor's employees relied on subjective criteria to identify orders it considered suspicious.

Committee Report at 8.

disclosure, the balance tips decidedly against Certain Defendants' objections. This Court, therefore, should reject those objections.

IV. THE DEA'S ARGUMENTS THAT A RECENT NEWPAPER ARTICLE "MAY BE ALREADY CAUSING HARM" AND ITS CONCLUSORY ASSERTIONS THAT DISCLOSURE OF 2013-2014 ARCOS DATA WILL HARM LAW ENFORCEMENT HAVE NO MERIT.

While the DEA has agreed to the de-designation of certain SORS data, the agency asserts there is good cause to extend the existing protective order to the 2013-2014 ARCOS data. The Sixth Circuit remand requires the DEA to shoulder the burden of establishing good cause. *In re Nat'l Prescrip. Opiate Litigat.,* 927 F.3d at 929 ("A protective order shall only be entered upon a showing of "good cause" *by the party seeking protection*.") (emphasis added). The DEA is, effectively, the moving party and therefore must make "a particular and specific demonstration of fact, as distinguished from stereotyped and conclusory statements'" *Id.*

Instead, the DEA has simply repeated the same inadequate good cause rationale it asserted more than a year ago – one that previously was held inadequate by the Court of Appeals.[8] However, its current filing does contain something new: a Declaration in support of

[8] Before the Sixth Circuit, DEA's counsel attempted to articulate a semblance of a rationale for the blanket protective order, but the court found this rationale unpersuasive:

> [T]t is difficult to understand this response given the nature of the ARCOS data. This response seems to assume that the DEA is unable to disclose data about a manufacturer under investigation – but it is unclear why this should be the case . . . [I]mportantly, the DEA has never explained why it could not simply redact the portions of the ARCOS data that relate to this and other ongoing investigations.

In re Nat'l Opiate Litig., 927 F.3d at 936. The Sixth Circuit indicated the necessity for DEA to explain why "a narrower protective order" would not be sufficient to "allow the DEA to object to disclosure as specific investigations may require." Id. Ultimately, the court directed that "[o]n remand the district court may entertain arguments by the DEA as to why particular pieces of ARCOS data that relate to specific ongoing investigations should not be disclosed." *Id*. at 938.

its previously rejected claim that "disclosure of ARCOS information creates a very real risk of undermining open investigations and legal proceedings that rely on ARCOS information because it could tip off companies that DEA may be investigating them."[9] (Declaration of Joey Lenseigne in Support of The United States of America's Brief Opposing the Disclosure Of 2013-2014 ARCOS Data, Doc #2040, Ex. 1, at 4, ¶ 15.) ("Lenseigne Declaration").

The DEA provides hypothetical "examples" that purport to support its claim of good cause for a protective order covering 2013-2014 ARCOS data. Nowhere does DEA offer "particular and specific demonstration of fact" to support a finding of Rule 26 (c) good cause. In *Prescription Opiate Litigation*, the court emphasized that "the DEA has never explained why it could not simply redact the portions of the ARCOS data that relate to this and other ongoing investigations." 927 F.3d at 937 (citing *Madel v. U.S. Dep't of Justice*, 784 F.3d 448, 453 (8th Cir. 2015), which held the DEA could "not automatically withhold an entire document when some information is exempt" from production). Ignoring the Sixth Circuit's admonition, the DEA does not explain how a distributor's or pharmacy's awareness it may be the subject of an DEA investigation could adversely impact current agency law enforcement efforts.

DEA also states "the relative age of the ARCOS data is not dispositive because investigations and legal proceedings take time to develop and there are frequently open investigations and pending litigation that rely on ARCOS data that is 10 years old . . . ." Lenseigne Declaration, Doc #2040, Ex. 1, at 4, ¶ 15. DEA's first "example" focuses on an

[9] "If the press were to receive access to the data, their efforts to interview an individual *could tip off a potential target before DEA had the opportunity to investigate*. Therefore, public disclosure of the data would be detrimental to DEA's investigative efforts and could ultimately impede DEA's efforts to bring enforcement actions." (DEA brief, Doc #717 PageID #16506.) (emphasis added).

investigation that used 2009-2011 ARCOS data resulting in the DEA securing a civil fine from a pharmacy owner in 2017.

The fact that the DEA may use ten-year-old ARCOS data to investigate unlawful drug company activity is not relevant to the agency's claim that a blanket protective order must be maintained regarding 2013-2014 ARCOS data. Regulated pharmacies, distributors and manufactures are aware of the number of opioid pills they have sold and/or delivered during 2013-2014. Nothing will prevent DEA from using ARCOS data from those years in an enforcement action should the 2013-2014 ARCOS data be disclosed.

Next, the DEA asserts that "[h]ad the ARCOS information at issue in the Miami-Luken case been released prior to the successful indictment, such release *could have tipped off Miami-Luken and its executives that DEA was investigating* their conduct and could have comprised DEA's investigation." (Lenseigne Declaration, Doc #2040, Ex. 1, at 4-5, ¶¶ 16-17.) (emphasis added). That Miami-Luken and its executives would be "tipped off" and their indictment compromised by the public disclosure of ARCOS data is difficult to comprehend, given the DEA's publicly stated ongoing scrutiny of the company:

> Miami-Luken, Inc. . . . is a pharmaceutical wholesaler that has come under DEA scrutiny for allegedly "facilitat[ing] the diversion of significant quantities of the highly addictive pain killers, oxycodone and hydrocodone." (Doc. #11, PageID #202.) The DEA's investigation of Plaintiff has been ongoing since 2008 or 2009. The DEA generally alleges that Miami-Luken illegally distributed hundreds of thousands, if not millions, of dosage units of oxycodone and hydrocodone in the Appalachian region of Ohio, Kentucky, and West Virginia, and that it will continue to do so until such time as its registration is revoked. (Doc. 11, PageID 209, citation omitted.)

In the Matter of Miami-Luken, Order to Show Cause, U.S. Drug Enforcement Administration, Case No. 1:16-mc-012, 2016 WL 3855205, at *1 (N.D. Ohio November 23, 2015).

Moreover, Miami-Luken's possible complicity in fueling the opioid epidemic in Appalachia has been a matter of public knowledge and a Congressional investigation. Eric Eyre, *Drug firms shipped 20.8M pain pills to WV town with 2,900 people*, *Charleston Gazette-Mail* (Jan. 29, 2018), https://www.wvgazettemail.com/news/health/drug-firms-shipped-m-pain-pills-to-wv-town-with/article_ef04190c-1763-5a0c-a77a-7da0ff06455b.html. Indeed, Media Intervenor *Charleston Gazette-Mail* reported:

> Springboro, Ohio-based Miami-Luken sold 6.4 million hydrocodone and oxycodone pills to Tug Valley Pharmacy from 2008 to 2015, the company disclosed to the panel. That's more than half of all painkillers shipped to the pharmacy those years. In a single year (2008 to 2009), Miami-Luken's shipments increased three-fold to the Mingo County town. Miami-Luken also was a major supplier to the now-closed Save-Rite Pharmacy in the Mingo County town of Kermit, population 400. The drug wholesaler shipped 5.7 million hydrocodone and oxycodone pills to Save-Rite and a branch pharmacy called Save-Rite #2 between 2005 and 2011, according to records Miami-Luken gave the committee. In 2008, the company provided 5,624 prescription pain pills for every man, woman and child in Kermit.

1. *Id*.

2. In 2016, the *Charleston Gazette-Mail* reported the massive delivery of prescription opioids by Miami-Luken and other major opioid distributors to Kermit and other small towns in the Southern West Virginia coalfields — quoting DEA ARCOS data obtained via a state freedom of information act request. Doc #725-3, PageID #16635 at ¶¶ 16-18.[10] That the DEA's

[10] *See also* Committee Report, *supra*, at 17, 18-19, containing findings setting forth a litany of Miami-Luken's potentially unlawful activity:

- According to Miami-Luken's Chairman of the Board, prior to 2013, the company made "rudimentary efforts" to monitor suspicious orders and decisions on what constituted a suspicious order were made based on 'one's feeling.'
- Between 2009 and 2015, Miami-Luken shipped more than 4.38 million doses of hydrocodone and oxycodone to Westside Pharmacy, located in Oceana, West Virginia, population 1,394.
- As early as 2011, Miami-Luken was aware that Westside Pharmacy was filling prescriptions for doctors located hours away, and that a large number of

declarant – a high-ranking supervisor of the agency involved in investigations and diversion control - is unaware of these historical facts is as inexplicable. Arguably even more inexplicable is the DEA's assertion that release of 2013-2014 ARCOS data could "tip off" a blissfully unaware Miami-Luken – given that the company has been the subject of public scrutiny and DEA investigation and enforcement action for more than a decade.

The DEA's third "example" of the threat posed by disclosure of 2013-2014 ARCOS data is a July 17, 2019, *Washington Post* article that used 2006-2012 ARCOS data in reporting on the history of the opioid epidemic. Chief Lenseigne's Declaration states "the Washington Post reported that the ARCOS data suggested that six of the largest distribution companies had fueled the opioid epidemic" and that "the harm has already come to pass." Lenseigne Declaration, Doc #2040, Ex. 1, at 5, ¶ 19. That harm, the declaration asserts, is "tipping off of public disclosure of ARCOS data by the media could tip off companies that DEA may be investigating them."[11] *Id*. at Doc #2040, Ex. 1, at 5-6, ¶¶ 18-20.

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prescriptions for hydrocodone and oxycodone were paid for with cash. Despite this knowledge, the company continued to supply the pharmacy with more than 3.36 million opioids over the next four years.

- Miami-Luken's May 2015 analysis of Westside Pharmacy's dispensing data showed that three doctors wrote 74 percent of the oxycodone prescriptions filled by the pharmacy between February 2015 and April 2015. Following the company's analysis, the pharmacy pledged it would no longer fill prescriptions written by those doctors.
- In October 2015, after determining that Westside Pharmacy continued to fill prescriptions written by the three physicians, Miami-Luken did not immediately terminate the pharmacy or restrict its ability to order controlled substances.
- In November 2015, Miami-Luken approved an increase to Westside Pharmacy's oxycodone threshold despite being aware of the pharmacy's prior deceit and red flags related to its dispensing practices and prescribing physicians.

[11] The DEA erroneously suggests that harm "has already happened" for unidentified companies "that may be subject to mistaken suspicion" because of the reporting on the 2006-2012 ARCOS data by the *Post*. But, the DEA concedes "[s]uch companies are already under increased media and public scrutiny, regardless of whether they engaged in criminal behavior." Companies

The suggestion that opioid distributors of hundreds of millions of addictive pills are unaware of the possibility that the DEA might be investigating them is extraordinary. A presidential declaration of a national health emergency, the deaths of tens of thousands of Americans from prescription opioid overdoses and the addiction of millions more have triggered enormous public attention and concern. It is inconceivable prescription opioid distributors are unaware their activities have been under DEA scrutiny. *See* Dep't of Justice News Release, *McKesson Corporation Agrees to Pay More than $13 Million to Settle Claims that it Failed to Report Suspicious Sales of Prescription Medications* (May 2, 2008), ("'[T]he McKesson Corporation fueled the explosive prescription drug abuse problem we have in this country,' said DEA Acting Administrator Michele M. Leonhart."), https://www.justice.gov/archive/opa/pr/2008/May/08-opa-374.html. In 2012, the DEA Administrator testified before the United States Senate that

> DEA's enhanced regulatory oversight and investigative efforts have resulted in the identification of various distributors who failed to adhere to their regulatory responsibilities. Consequently, DEA took administrative action against these distributors, and also referred them for civil penalty action which resulted in record-breaking civil penalties negotiated with the registrant, e.g., $13.25 million civil penalty paid by McKesson Drug Corporation in April 2008; $34 million civil penalty paid by Cardinal Health in October 2008; and $75 million civil penalty in addition to $2.6 million in civil forfeitures against CVS Corporation in October 2010. And in April 2011, the Harvard Drug Group agreed to pay a civil penalty of $8 million.

Responding to the Prescription Drug Epidemic: Strategies for Reducing Abuse, Misuse, Diversion, and Fraud, Statement of Michele M. Leonhart, Administrator Drug Enforcement Admin., U.S. Sen., Subcomm. on Crime and Terrorism, Comm. on the Judiciary at 6 (May 24,

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operating in the highly regulated opioid supply chain delivering millions of pills to local pharmacies have been subject to media and public scrutiny for more than a decade.

2011), https://www.dea.gov/sites/default/files/pr/speeches-testimony/2012-2009/110524_testimony.pdf.

The DEA's claim that harm to its law enforcement efforts "has already come to pass" as a result of a July 16, 2019, newspaper article are incomprehensible in light of the robust media reporting on the scope of the national opioid crisis and the focus of public discourse and congressional investigations on opioid distributors' role in the opioid epidemic. For example, a 2016 article focused directly on opioid distributors role in delivering massive quantities of prescription opioids to local pharmacies:

> Collectively, 13 companies identified by *The Washington Post* knew or should have known that hundreds of millions of pills were ending up on the black market, according to court records, DEA documents and legal settlements in administrative cases, many of which are being reported here for the first time. Even when they were alerted to suspicious pain clinics or pharmacies by the DEA and their own employees, some distributors ignored the warnings and continued to send drugs.

How drugs intended for patients ended up in the hands of illegal users: 'No one was doing their job, *Wash. Post* (October 22, 2016), https://www.washingtonpost.com/investigations/how-drugs-intended-for-patients-ended-up-in-the-hands-of-illegal-users-no-one-was-doing-their-job/2016/10/22/10e79396-30a7-11e6-8ff77b6c1998b7a0_story.html?utm_term=.ad347406ce41.

The opioid distribution industry is heavily regulated. The probability any company in the trade would be unaware that their unlawful activity could be the target of a DEA investigation is implausible. One is left to wonder why the agency would so aggressively seek to block public disclosure of the remaining 2013-2014 ARCOS data.

With regard to that 2013-2014 time period, the Committee Report found, "the number of ISOs [immediate suspension orders] initiated by the DEA began to substantially decline in

2013, with the agency failing to bring any ISOs against distributors for nearly a six-year period." Committee Report at 35. The Chair of the House Committee wrote to the DEA in May 2017 "referencing not only the West Virginia opioid distribution figures, but also reporting from the Charleston Gazette-Mail and Washington Post that detailed sharp declines in the number of enforcement actions initiated by the DEA, beginning in 2013, while the opioid epidemic was continuing to surge." Committee Report at 41.

The Report also observed that "in recent years, even as the opioid epidemic has worsened, the number of ISOs issued by the DEA dramatically dropped." Committee Report at 66. The Committee found, "The number of ISOs issued by DEA declined from a high of 58 in FY 2011 to a low of five in FY 2015." Committee Report at 67. Exposing the 2013-2014 ARCOS data to the sunlight of public scrutiny would provide insight into the relationship between the evolving prescription opioid epidemic and evidence of whether DEA enforcement failure occurred at a crucial time in the crisis. The DEA has failed to carry its burden of establishing good cause under Rule 26(c) with regard to 2013-2014 ARCOS data. It should be disclosed to the public in its entirety.

V. CONCLUSION

For the foregoing reasons, HD Media respectfully requests that this Honorable Court rule that good cause neither exists to support the objections of Certain Defendants to the disclosure of SORS nor the DEA's argument for maintaining a protective order governing the 2013-2014 ARCOS data.

Date: August 5, 2019

/s/Patrick C. McGinley
Patrick C. McGinley (W. Va. Bar 5620; Pa. Bar 33674)
Suzanne Weise (W. Va. Bar 4312)
737 South Hills Drive
Morgantown, West Virginia 26501
Cell Phone: 304-552-2631
Telephone & Fax: 304-292-9822

Counsel for HD Media Company, LLC

CERTIFICATE OF SERVICE

I certify that on August 5, 2019, a copy of the foregoing "REPLY TO BRIEF OF CERTAIN DEFENDANTS' OBJECTIONS TO PROPOSED ORDER DE-DESIGNATING DEA SUSPICIOUS ORDER REPORTS AND DEA BRIEF IN SUPPORT OF MAINTAINING THE COURT'S PROTECTIVE ORDER" was electronically filed and served on all counsel of record for this case through the Court's electronic filing system.

/s/ Suzanne Weise
Suzanne Weise (W. Va. Bar 4312)
737 South Hills Drive
Morgantown, West Virginia 26501
suzweise@yahoo.com
Telephone & Fax: 304-292-9822

Counsel for HD Media Company, LLC